



Declaration of Conformity

(Issued according to Medical Devices Directive 93/42/EEC, as last amended by directive 2007/47/EC)

We hereby declare that the devices mentioned below fall within class III and meet the provisions of Medical Devices Directive of the European Union, 93/42/EEC as last amended under directive 2007/47/EC. We also declare that conformity assessment procedure is carried out according to annex II of the directive and implemented quality management system, complying ISO 13485:2016. The manufacturer is solely responsible for the declaration of conformity.

Manufacturer: Aegis Lifesciences Pvt. Ltd., 215/216, Mahagujarat Industrial Estate-382 213, Ahmedabad, Gujarat, India
EC Rep.: Obelis S.A, Bd. General Wahis 53, 1030 Brussels, Belgium
Product Name: Surgi-ORC®
Generic Name: Oxidized Regenerated Cellulose Haemostat, Sterile, Absorbable
Intended Use: The Surgi-ORC haemostat is used adjunctively in various surgical procedures to assist when control of bleeding from capillary, venous and small arteriolar vessels, by pressure, ligature and other conventional procedures is either ineffective or impractical. The Surgi-ORC haemostat can be cut to size in endoscopic procedures.
GMDN code: 38771
Class: III (Rule 8, Annex IX, MDD 93/42/EEC)
Notified Body: DNV GL Presafe AS, Veritasveien 3, 1363 Høvik, Norway.
Sizes/Model: As given in below table.

Sr. No.	Model Variant	Product ID	Dimensions
1.	Original / Standard	SOO-0214	2 inch X 14 inch (5.1 cm X 35.6 cm)
2.		SOO-0408	4 inch X 8 inch (10.2 cm X 20.3 cm)
3.		SOO-0203	2 inch X 3 inch (5.1 cm X 7.6 cm)
4.		SOO-502	0.5 inch X 2 inch (1.3 cm X 5.1 cm)
5.	Knit	SOK-0203	2 inch X 3 inch (5.1 cm X 7.6 cm)
6.		SOK-0304	3 inch X 4 inch (7.6 cm X 10.2 cm)
7.		SOK-0609	6 inch X 9 inch (15.2 cm X 22.9 cm)
8.		SOK-0101	1 inch X 1 inch (2.5 cm X 2.5 cm)
9.		SOK-0103	1 inch X 3 inch (2.5 cm X 7.6 cm)
10.		SOK-0135	1 inch X 3.5 inch (2.5 cm X 8.9 cm)
11.	Fibril	SOF-0102	1 inch X 2 inch (2.5 cm X 5.1 cm)
12.		SOF-0204	2 inch X 4 inch (5.1 cm X 10.2 cm)
13.		SOF-0404	4 inch X 4 inch (10.2 cm X 10.2 cm)
14.	Non-Woven / SNOW	SON-0102	1 inch X 2 inch (2.5 cm X 5.1 cm)
15.		SON-0204	2 inch X 4 inch (5.1 cm X 10.2 cm)
16.		SON-0404	4 inch X 4 inch (10.2 cm X 10.2 cm)

Standards applied: UNITED STATES PHARMACOPOEIA 43, EN 556-1: 2001, EN 1041: 2008, EN ISO 10993-1: 2009, EN ISO 10993-3: 2014, EN ISO 10993-4: 2009, EN ISO 10993-5: 2009, EN ISO 10993-6: 2009, ISO 10993-10: 2010, EN ISO 10993-11: 2018, EN ISO 11137-1: 2015, EN ISO 11137-2: 2015, EN ISO 11607-1: 2009, EN ISO 11607-2: 2006, EN ISO 11737-1: 2006, EN ISO 11737-2: 2009, EN ISO 13485: 2016, EN ISO 14971: 2012, EN ISO 15223-1: 2015

Certificate details:

CE Certificate : 10000384931-PA-NA-IND Rev 2.0
Design Approval Certificate : 10000428353-PA-NA-IND Rev 2.0
Quality Management System Certificate : 247061-2017-AQ-IND-NA-PS Rev. 2.0

Authorized Signatory

Name : Mr. Bhawin Trivedi
Position : Authorised Signatory
Date : 04/03/2021
Place : Ahmedabad, India.



Doc. No.: AL/ECDOC/ORC/R2 V-01, Date of revision: 04/03/2021

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